

REMARKS

Claims 7-62 were previously pending in this application. By this response, Applicant amends claim 24. As a result, claims 7-62 are pending for examination with claims 7, 24, 43, and 62 being independent claims. No new matter is added.

Rejections Under 35 U.S.C. §103 Are Overcome

Claims 7-16, 18-35, 37-42, and 62 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Atala (US 5,571,119) in view of Mericle (US 5,752,964). Additionally, claims 17 and 36 stand rejected over Atala and Mericle in further view of Gordon (US 5,741,277) and claims 43-61 stand rejected over Makower (US 6,090,063) in view of Gordon.

Independent Claim 7

In the Office Action, it is stated that Atala shows each of the features of claim 7, except for a cutter that moves in the instrument. It is suggested, however, that one of skill in the art would look to Mericle to satisfy this deficiency. Applicant respectfully disagrees with this rejection.

Initially, Applicant respectfully points out that the Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385 (2007) held that “rejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” The key to supporting any rejection under 35 U.S.C. §103 is the clear articulation of the reason(s) why the claimed invention would have been obvious, and an explicit analysis in supporting such a rejection (emphasis added). Additionally, MPEP §2143 lists several examples of rationales that may be used to establish a prima facie case of obviousness, although other rationales may be relied upon to support an obviousness rejection.

None of the rationales set forth in MPEP §2143 appear to have been used to support the claim rejections under 35 U.S.C. in the Office Action. Neither are any other rationales discussed. In the case of independent claim 7, the Office Action merely states that one having ordinary skill in the art would look to Mericle to provide a cutter that moves in the instrument in order to eliminate a need for additional cutting instruments and to offer multi-functionality and simplicity for the

surgeon. Applicant respectfully asserts that not only does this mere conclusory statement fall well short of the clear articulation and explicit analysis required to support an obviousness rejection, such that a *prima facie* case of obviousness has not been established, but that, based on the reasons stated, one having ordinary skill in the art would actually have been led away from the modifications suggested.

The device of Atala already includes a cutter (see generally col. 5, lines 46-48). It is unclear to the Applicant how modifying the cutter of Atala to move within the instrument would eliminate a need for additional cutting instruments, offer multi-functionality, and simplicity. The cutter of Atala has a flat, blade-like shape with surfaces sharpened into cutting edges. (Col. 5, lines 46-48). There is no discussion in the Office Action as to how or why there might be a need for additional cutting instruments with the device of Atala. Rather, it is just stated in a conclusory manner that one having ordinary skill in the art would look to modify Atala for such a reason. Additionally, the flat-blade like structure of the cutter in Atala would already appear to offer multi-functionality and simplicity, especially when compared to the cutter of Mericle. In Mericle the cutter includes features to place a knot and cut excess suture material from the knot (col. 2, lines 45-51). This appears to be for a very specific function, rather than multi-functionality suggested in the Office Action. In light of this, Applicant respectfully asserts that one having skill would actually have been led away from a design like that of Mericle based on the reasons suggested in the Office Action.

For at least the above reasons, the rejection of independent claim 7 is believed to be overcome. Gordon fails to satisfy the deficiencies of Atala and Mericle, such that the rejections of each of the claims dependent on claim 7 are also believed to be overcome. Accordingly, withdrawal of these rejections is respectfully requested.

Independent Claim 24

Initially, Applicant respectfully asserts that, for the same reasons set forth above with respect to independent claim 1, the Office Action fails to establish a *prima facie* case of obviousness and that one having ordinary skill in the art would actually have been led away from modifying Atala, based on the reasons suggested in the Office Action.

Independent claim 24 now recites a suturing instrument that comprises, among other features, a passageway having a first radius of curvature and a second lateral radius of curvature in a different direction than the first radius of curvature to carry a suture wire to the opening. The passageway, first radius of curvature and second lateral radius of curvature are constructed and arranged so that, when moved in the passageway, suture wire exits an opening and loops back to the distal end of the shaft along a helical trajectory and without requiring additional contact with the instrument to form an annular fastener.

In the Office Action, it is stated that Figs. 8 and 9 of Atala disclose a passageway having an angle of curvature that may create loops of suture if a plastically deformable suture wire is passed through the opening for a certain length. Applicant respectfully asserts that Attala merely shows an opening with an angled surface. It is unclear, however, how such a structure may lead a wire to follow a helical trajectory. Applicant has amended claim 24 to now recite that the passageway has a first radius of curvature and a second lateral radius of curvature in a different direction than the first radius of curvature. It is the passageway having these different radii of curvature (e.g. forming a helix, as shown in Fig. 6 of the present application) that allow the suture wire to exit the opening and loop back along a helical trajectory. There are no teachings or disclosures of such features in Attala or Mericle.

For at least the above reasons, the rejection of independent claim 24 and any claims depending therefrom are believed to be overcome. Accordingly, withdrawal of these rejections is respectfully requested.

Independent Claim 43

It is conceded in the Office Action that Makeower fails to teach or disclose a passageway having a curved or “S” shaped portion arranged so that suture wire moving through and exiting the opening forms suture wire loops. It is suggested, however, that Gordon teaches such features and that it would be obvious to one of ordinary skill in the art that convoluted channels in suturing instruments are used to facilitate forming loops in sutures so as to eliminate the need for additional looping, knotting instruments and to securely attach to tissue. Applicant respectfully disagrees and asserts that a *prima facie* case of obviousness has not been established.

Makower relates to a device / method for introducing filament, and as conceded in the Office Action, fails to teach or disclose an “S” shaped portion of a passageway. Gordon relates to a device that includes a needle and suturing material (e.g., not wire) for endoscopically placing sutures. Although Gordon may show an “S” shaped portion, there is no teaching or disclosure of an “S” shaped portion arranged so that suture wire moving through and exiting the opening forms suture wire loops. Nonetheless, it is suggested that Gordon is capable of performing in this manner and that it is well known in the art that convoluted channels in suturing instruments are used to facilitate forming loops in sutures so as to eliminate the need for additional looping, knotting instruments and to securely attach to tissue. Here again, none of the rationales set forth in MPEP §2143 in appear to have been used to support this claim rejection under 35 U.S.C. 103(a). Neither are any other rationales discussed. Applicant respectfully asserts that the conclusory statement offered in the Office Action falls well short of the clear articulation and explicit analysis required to support an obviousness rejection, such that a *prima facie* case of obviousness has not been established.

Applicant also respectfully asserts that the Office Action fails to establish that, in the device of Gordon, a suture wire moving therethrough and exiting an opening would necessarily form a suture wire loop, as is required to establish that an aspect of a prior art reference is disclosed inherently. (See generally, MPEP 2112). Applicant respectfully reminds the Patent Office that, “to establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities.” (MPEP 2112). In this respect, not all of the claimed features are present in Makower and Gordon, even if they were properly combinable.

For at least the above reasons, the rejection of independent claim 43 and any claims depending therefrom are believed to be overcome. Accordingly, withdrawal of these rejections is respectfully requested.

Independent Claim 62

Initially, Applicant respectfully asserts that, for the same reasons set forth above with respect to independent claim 1, the Office Action fails to establish a *prima facie* case of obviousness and that one having ordinary skill in the art would actually have been led away from modifying Atala, based on the reasons suggested in the Office Action.

In the Office Action, it is stated that Fig. 9 of Atala reads on the method steps of claim 62 that recite “bending suture wire in a passageway to form a suture wire loop with a suture wire that exits a distal end of a suturing instrument, the suture wire loop being formed without requiring further contact of the instrument with the suture wire after the suture wire extends from the distal end of the suturing instrument”. Specifically, it is stated that Fig. 9 reads on this limitation since a loop is formed in the passageway [of Atala] and the tip of the suture wire exits a distal end of the suturing instrument. Applicant respectfully disagrees with this rejection.

Initially, Applicant respectfully points out that a prior art device must necessarily carry out a claimed process / method during normal operation to anticipate or establish a *prima facie* case of obviousness. (See generally, MPEP 2112.02). Only *speculation* appears to be offered in the Office Action that, in the device of Atala, a suture wire loop would be formed without requiring further contact with the instrument with the suture wire after the suture wire extends from the distal end of the suturing instrument. There is no disclosure to support such speculation, and certainly there is no disclosure to support the assertion that this occurs during normal operation of the device of Atala. In this additional respect, a *prima facie* case of obviousness has not been established.

For at least the above reasons, the rejection of independent claim 62 and any claims depending therefrom are believed to be overcome. Accordingly, withdrawal of these rejections is respectfully requested.

CONCLUSION

In view of the above amendment, applicant believes the pending application is in condition for allowance.

If a fee is due, in addition to the fees submitted herewith, please charge our Deposit Account No. 23/2825 under Docket No. D0188.70165US02 from which the undersigned is authorized to draw.

Dated: October 19, 2009

Respectfully submitted,

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